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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,113	10/20/2001	John Vincent Fontana	8364M	6409
27752	7590	12/21/2005		
THE PROCTER & GAMBLE COMPANY INTELLECTUAL PROPERTY DIVISION WINTON HILL TECHNICAL CENTER - BOX 161 6110 CENTER HILL AVENUE CINCINNATI, OH 45224			EXAMINER HAND, MELANIE JO	
			ART UNIT	PAPER NUMBER
			3761	

DATE MAILED: 12/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/054,113	Applicant(s) FONTANA ET AL.	
	Examiner Melanie J. Hand	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4,5,7-21,23 and 24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4,5,7-21,23 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

The drawings were received on September 16, 2005. These drawings are acceptable.

Response to Arguments

Examiner acknowledges the correction to claim 8 to overcome the objection to the claim and is thus withdrawing the objection.

Applicant's arguments filed September 16, 2005 have been fully considered but they are not persuasive.

With regard to the rejection of claims 4-12 and 18-21 and applicant's argument that Schroeder teaches applying adhesive to entire surfaces, Examiner disagrees. Schroeder teaches various arrangements of adhesive attachment points, an example of which is not having side edge portions of substrate 4 at all and having adhesives 3,5 disposed at the ends and a seal at end region 6, allowing the side edges of backsheet 1 to remain adhesive-free, ('522, Col. 5, lines 35-40) which is a substantially identical configuration to the claimed invention. With regard to applicant's argument that Schroeder does not teach a circumferential edge, as can best be seen in Figs. 1,2,4 and 5, at least one of the dimensions of gauze pad 14 is smaller than the corresponding dimension of backsheet 1, therefore said article does in fact have a circumferential edge.

Examiner agrees with Applicant's argument that the allegation that applicant is not clear about the location of the leading and trailing edges of the claimed patch is invalid, however such argument is moot in view of the new rejection of claims 4,5,7-11, 18, 19 23 and 24 under 35 U.S.C. 102(e) as anticipated by Schroeder.

With regard to Applicant's arguments pertaining to the perceived failure on the part of the Office to make a prima facie case for obviousness under 35 U.S.C. 103 in its rejection of claims 4-12 and 18-21, such argument is also moot in view of new rejection of currently pending claims 4,5,7-11, 18, 19 23 and 24 under 35 U.S.C. 102(e) as anticipated by Schroeder.

With regard to Applicant's arguments pertaining to the perceived failure on the part of the Office to make a prima facie case for obviousness under 35 U.S.C. 103 in its rejection of claims 5,7,9,10,13-21 and 23, and the belief that applicant's own admission as acknowledged by Examiner does not remedy the failure of Schroeder to teach or fairly suggest all of the limitations of the aforementioned claims, Examiner disagrees. While applicant does claim precisely polyethylene, polyester and siliconized polyester as materials in claims 13-15 and while Schroeder indeed does not explicitly teach those materials, Schroeder does fairly suggest them by stating that: "the top cover sheet may be made of any convenient packaging material such as paper or plastic" ('522, Col. 5, lines 20,21), that "materials such as paper, plastic, fabric, metal foils or layered combinations of the above are well-known in tape and bandage application" ('522, Col. 4, lines 53-56), and that one material that works well for the release layer is paper coated with silicone on the side facing the article "('522, Col. 4, line 67- Col. 5, line 3). These statements are clear evidence that Schroeder fairly suggests polyethylene for the applicator substrate 4, polyethylene for the backsheet 1 of the article, and siliconized polyester for the release layer 13, and applicant's admission that "suitable materials for use as the applicator substrate, patch and release substrate are intended in their broadest sense" serves as support for the argument that Schroeder fairly suggests those materials, because if the applicant can refer to structural features of the claimed invention "in the broadest sense", then prior art that teaches a scope that is equally broad is valid prior art.

With regard to Applicant's argument that each of the references fails to teach or fairly suggests the presence of tabs that are offset laterally or a circumferential edge, these limitations have been addressed in prior Office actions and this Office action as being satisfied by the prior art of Schroeder. Applicant is also reminded that each of the references does not have to teach all of the limitations for a rejection under 35 U.S.C. 103 to be valid.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 4, 5, 7-11, 18, 19, 23 and 24 rejected under 35 U.S.C. 102(e) as being anticipated by Schroeder ('522).

With respect to **Claims 4,11**: With regard to limitation (a), Schroeder teaches applicator substrate 4 having one surface coated with adhesive 15 and having tab 8 that extends laterally outward from substrate 4. (Col. 5, lines 19-21, Col. 6, lines 39-47) With regard to limitation (b), Schroeder teaches an article comprising a backing sheet 1 with a first adhesive 3 disposed on one that secures gauze pad 14 to said backing sheet. (Col. 4, lines 32-34) With regard to limitation (c), Schroeder teaches bottom cover sheet 9 having an interior surface and a tab region 12 that extends laterally outward from said cover sheet and is laterally offset from tab 8. (Fig. 1) (Col. 5, lines 12-17) With regard to the remaining limitations, Adhesive 15 releasably affixes said interior surface of substrate 4 to a first surface of said article (Col. 5, lines 52,53), comprising a first peel bond and forming a structure that consists of said article and said applicator substrate and has an upper surface. Bottom cover sheet 9 is affixed to said structure via adhesive 16 disposed on its interior surface (Col. 5, lines 53,54), thus forming a second peel

bond. Schroeder teaches article backsheet 1 that provides a circumferential edge defined by the edge of gauze pad 14. (Figs. 2,4,5) Backsheet 1 has a leading edge in end region 6 (where tabs 8 and 12 are located) and a trailing edge longitudinally opposed, or distal relative to, the leading edge and tabs 8 and 12. (Fig. 1) Leading and trailing edges have adhesive 3 disposed on the interior surface, however, the side edges would not as that adhesive area would be occupied by the upper surface of gauze pad 14 and therefore are non-secured edges. Similarly, adhesive region 15 disposed on the interior surface of substrate 4, has an adhesive contact area having a leading edge in end region 6 and a trailing edge distal of said leading edge. Since these leading and trailing edge regions are part of an adhesive contact area, said regions are capable of tacking the corresponding edges of said article to the interior surface of substrate 4.

With respect to **Claim 5**: Since Schroeder teaches that the applicator substrate 4 “pops up” upon application of said article to target surface 20 (Col. 7, lines 26,27), Schroeder is thus teaching that the strength of the adhesive bond between backsheet 1 and target surface 20 is greater than the first peel bond strength.

With respect to **Claims 7,24**: Schroeder teaches that “articles of nearly any size and shape may be packaged and applied using the technique described herein” (Col. 4, lines 47-50), which would encompass the limitations set forth in claims 7 and 24.

With respect to **Claim 8**: Schroeder teaches that substrate 4 is larger than backsheet 1 and has adhesive 15 disposed on its interior surface, (Col. 5, lines 30,31) therefore the adhesive area 15 defines an adhesive area surrounding said article.

With respect to **Claims 9,10**: Schroeder teaches that gauze pad 14 may be treated with a biochemically active compound. (Col. 4, lines 37,38)

With respect to **Claims 18 and 19**: Since backsheet 1 is rectangular, any of the four edges adjacent the edge of gauze pad 14 will comprise about 25% of the total perimeter of backsheet 1. Since the leading edges are shorter than the side edges, the trailing and leading edges will likely constitute less than 50%, and thus between them each will constitute less than 25% of the total perimeter.

With respect to **Claim 23**: Schroeder teaches applying a medicament to said article. The term medicament is considered herein to encompass hormones, and thus since Schroeder also teaches a method of applying said article, Schroeder also teaches a method of delivery of a hormone.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schroeder ('522).

With respect to **Claims 20 and 21**: Schroeder does not explicitly teach that the leading edge contact area comprises an area in the range of 0.4-2 cm² or 0.4-2.5 cm². Examiner is concluding as in the previous office action that this merely constitutes an optimization of the

value of the contact area variable. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. See *In re Aller* (105 USPQ 233)

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schroeder ('522) in view of Wick ('929).

With respect to **Claim 12**: Schroeder does not teach including instructions with the packaging for said article. Wick teaches a patch applicator accompanied with instructions in the form of indicia that are printed on the patch. ('929, Col. 6, lines 21-29) Wick teaches that this allows the user to understand which tab is to be grasped first to facilitate application, therefore it would be obvious to one of ordinary skill in the art to modify the article taught by Schroeder to contain instructional indicia printed on said article as taught by Wick.

Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schroeder ('522) in view of Applicant's disclosure.

With respect to **Claims 13-15**: Examiner reaffirms the rejection of claims 13-15 in the previous Office action, in addition to the following: Schroeder teaches that plastic materials are suitable for substrate 4 (Col. 5, lines 20,21), which includes polyester, polyethylene and siliconized polyester, and therefore it would be obvious to one of ordinary skill in the art to alternately produce substrate 4 taught by Schroeder so as to be comprised of any of these materials.

Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schroeder ('522) in view of Sessions ('406).

With respect to **Claim 16,17**: Schroeder does not teach any of the items in the group of active agents set forth as a medicament usable in said article. Sessions teaches a thin film wound dressing comprised of absorbent material 30 that contains medication. Sessions teaches that hormones are disposed on material 30. Since medication provides healing beyond the insulation of a wound covering, it would be obvious to modify the article taught by Schroeder by disposing medication throughout gauze pad 14 as taught by Sessions.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Melanie J Hand
Examiner
Art Unit 3761

MJH

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

